




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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/091,440	03/07/2002	Eishun Tsuchida	220257US0CIP	3678
22850	7590	07/20/2004		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER WALLENHORST, MAUREEN	
			ART UNIT	PAPER NUMBER
			1743	
DATE MAILED: 07/20/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/091,440	<b>Applicant(s)</b> TSUCHIDA ET AL. 	
	<b>Examiner</b> Maureen M. Wallenhorst	<b>Art Unit</b> 1743	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 13-17, 20, 22 and 26-28 is/are rejected.
- 7) ☒ Claim(s) 6-12, 18, 19, 21 and 23-25 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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1. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

2. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprising" on lines 2, 7 and 8. Correction is required. See MPEP § 608.01(b).

3. The disclosure is objected to because of the following informalities: On page 10, line 5 of the specification, the word —Daltons—should be inserted after the phrase "1,000 to 20,000" so as to be consistent with amended claims 8 and 19.

Appropriate correction is required.

4. Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is indefinite since the molecular assemblies have not been positively recited as containing lipid therein. Therefore, the recitation of the amount of polyoxyethylene with respect to the total amount of lipid in the molecular assemblies is not clear. It is suggested to amend claim 20 by inserting the phrase —the molecular assemblies comprise lipid and—after the word "wherein on line 1 in order to fix this problem.

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5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-2, 5, 13, 15, 17 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Sakai et al (see abstract from Jinko Ketsueki, vol. 7, no. 4, pages 105-110, 1999).

Sakai et al teach of a method for preserving an oxygen infusion containing hemoglobin vesicles, which is achieved by polyoxyethylene conjugation and deoxygenation. The method comprises the steps of modifying the surface of the vesicles with polyoxyethylene, and deoxygenating the suspension with nitrogen bubbling. The samples stored at 4 degrees and 23 degrees show a stable dispersion state for 1 year. The vesicles also contain a physiological reductant (i.e. homocysteine) therein.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 3-4, 14, 16, 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakai et al. (see abstract from Jinko Ketsueki, vol. 7, no. 4, pages 105-110, 1999). For a teaching of Sakai et al, see previous paragraphs in this Office action.

The abstract to Sakai et al fails to teach that the oxygen infusion is stored in an oxygen-impermeable container filled with an inert gas. However, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to realize that the oxygen infusion taught by Sakai et al would have to be stored in an oxygen-impermeable container under an inert gas since Sakai et al teach of deoxygenating the infusion with nitrogen and storing the infusion, and in order to maintain the deoxygenated state in the infusion, oxygen would have be prevented from entering the storage container, and a common way to do this is to store the infusion under an inert gas in a container that does not allow the entrance of oxygen therein.

11. Claims 6-12, 18-19, 21 and 23-25 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Applicant's arguments filed April 19, 2004 have been fully considered but they are not persuasive.

The objection to the abstract made in the last Office action mailed on October 22, 2003 is maintained since the amended abstract in the response dated April 19, 2004 still contains legal phraseology therein. Most of the previous rejections of the claims under 35 USC 112, second paragraph are withdrawn, with the exception of claim 20, as noted above. The previous rejection of the claims under 35 USC 102(b) as being anticipated by Sakai et al (from Bioconjugate Chemistry) is withdrawn in view of the submission of the PCT priority document and the translation of this PCT priority document which establishes an effective US filing date for the instant application of August 17, 2000. Since the effective US filing date of the instant application is less than one year after the publication of this Sakai et al article (i.e. published April 21, 2000) and the authors of the reference are the same inventors of the present application, Sakai et al (from Bioconjugate Chemistry) is not available as prior art against the present application under 35 USC 102(a) or 35 USC 102(b).

The rejection of the claims under 35 USC 102(b) as being anticipated by Sakai et al (from Jinko Ketsueki) is maintained since both the abstract of this article and the copy of the article included with the response dated April 19, 2004 indicates that this article was published in 1999. Applicants argue that the publication date for this reference is August 20, 2000 since the copy of the reference supplied with the response has a date stamp on the last page of August 20, 2000. Therefore, Applicants argue that since the effective US filing date of the instant application is August 17, 2000, the Sakai et al (from Jinko Ketsueki) reference was published after the effective filing date of the instant application, and therefore, the reference is not available as

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prior art against the present application. In response to this argument, it is noted that the date stamp on the last page of the Sakai et al (from Jinko Ketsueki) reference is August 20, 1999, not August 20, 2000 as indicated by Applicants. Therefore, Sakai et al is available as prior art against the instant claims. In addition, it is also noted that the Sakai et al abstract used in this rejection comes from volume 7, number 4, pages 105-110, 1999. It appears that the copy of the reference included with the response dated April 19, 2004 is from volume 7, number 3, 1999.

The previous rejections of the claims under 35 USC 102(b) and 35 USC 103 based upon the primary reference to Nho are withdrawn in view of Applicants' persuasive arguments concerning this reference. Since claims 3-4, 14, 16 and 26-28 are newly rejected under 35 USC 103 as being obvious over the abstract to Sakai et al., this Office action is not being made final.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst  
Primary Examiner  
Art Unit 1743

mmw

July 19, 2004

*Maureen M. Wallenhorst*  
MAUREEN M. WALLENHORST  
PRIMARY EXAMINER  
GROUP 1700